



# ADOPTED

BOARD OF SUPERVISORS  
COUNTY OF LOS ANGELES

22 December 4, 2012

*Sachi A. Hamai*  
SACHI A. HAMAI  
EXECUTIVE OFFICER

Los Angeles County  
Board of Supervisors

December 04, 2012

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First District

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Second District

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Third District

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Fourth District

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Fifth District

The Honorable Board of Supervisors  
County of Los Angeles  
383 Kenneth Hahn Hall of Administration  
500 West Temple Street  
Los Angeles, California 90012

Dear Supervisors:

**APPROVAL OF AMENDMENT TO INDIGENT DRUG RECOVERY  
SERVICES AGREEMENT  
(ALL SUPERVISORIAL DISTRICTS)  
(3 VOTES)**

**SUBJECT**

Request approval of an Amendment to the Indigent Drug Recovery Services Agreement with Cardinal Health 110, Inc., to extend the term for one year, with options to further extend the term for up to four additional years, at an estimated annual cost of \$720,000. The Department of Health Services is also requesting delegated authority to amend the Agreement, to exercise the term options, and to revise the scope of work to include additional cost-saving opportunities.

**IT IS RECOMMENDED THAT THE BOARD:**

1. Authorize the Director of Health Services ("Director"), or his designee, to execute Amendment No. 7 to Indigent Drug Recovery Services Agreement No. H-703104 (Agreement) with Cardinal Health 110, Inc. (Cardinal), effective upon Board approval, to extend the Agreement term for one year, for the period January 1, 2013 through December 31, 2013, with options to further extend the Agreement term on an annual basis for up to four additional years, at an estimated annual cost of \$720,000.

2. Delegate authority to the Director, or his designee, to exercise the term options and execute future amendments to the Agreement, to: a) extend the Agreement term on an annual basis, for up to four additional years; and/or, b) revise the Agreement terms to include additional pharmaceutical manufacturer

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care to Los Angeles County residents  
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and through collaboration with  
community and university partners.



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cost-saving opportunities and/or similar cost-saving programs offered by medical device/equipment manufacturers, which pertain to (i) Prescription Card Programs and/or (ii) Patient Assistance Programs for drugs and/or devices, at the same reimbursement rate and under the same terms and condition, subject to review and approval by County Counsel, and with notice to the Board and Chief Executive Office.

### **PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION**

As the economic recovery continues to struggle along with an expanding indigent/un-insured population, the Department of Health Services (DHS or Department) has continued to be challenged for innovative solutions to manage and control escalating pharmaceutical costs. The diversity & complexity to manage multiple chronic diseases has become a mainstay of modern medical care. Faced with the challenges of limited funds and the growing indigent population, the Board approved the Agreement to partner with DHS' drug distributor (Cardinal Health) for pursuing Patient Assistance Program (PAP) reimbursement in DHS facilities.

PAPs are programs offered by pharmaceutical companies, in which "free" drugs are provided to uninsured and needy patients, who otherwise would not be able to afford these expensive medications. To obtain their much needed medications, eligible patients must be enrolled and meet certain financial criteria through the application process administered by Cardinal Health.

Approval of the first recommendation will allow the Director to execute an Amendment, substantially similar to Exhibit I, for the continued provision of Indigent Drug Recovery Services at DHS facilities. To date, Cardinal Health has assisted DHS to enroll over 22,000 PAP patients, and recovered the costs of more than 120 different drugs through the pharmaceutical manufacturers replenishing medications dispensed to the enrolled patients or issuing a credit towards future DHS pharmaceutical purchases. Since the inception of the Agreement in 2008, the Department has documented over \$25 million dollars in cost savings. In addition to identifying and enrolling eligible patients, Cardinal Health provides cost-savings reports, and maintains all records for PAP audits performed by pharmaceutical manufacturers. The current Agreement will expire on December 31, 2012.

Approval of the second recommendation will allow DHS to further extend the Agreement term, as well as avail itself of additional cost-saving opportunities offered for the benefit of uninsured and needy patients by both pharmaceutical and medical device/equipment manufacturers as described below:

**Prescription Card Program.** Under the terms of the current Agreement, Cardinal charges 8% of the DHS' acquisition cost of drugs replenished by participating pharmaceutical manufacturers. Some of these manufacturers also offer additional cost savings opportunities through their prescription card program, whereby a prescription card, rather than the actual drug, is sent directly to the DHS pharmacy that enables DHS to bill and receive reimbursement by the manufacturer. Since such reimbursement may be higher than the acquisition cost (which is used as a basis to pay Cardinal Health), DHS can realize further savings through the prescription drug program.

**Medical Device.** Currently, the Agreement allows Cardinal to access patient assistance programs for drugs. DHS also desires an expansion of this program to include certain medical devices such as stents and pacemakers, whereby Cardinal will be reimbursed at the same 8% rate. The Department is exploring the feasibility of alternative cost-saving programs and will only exercise this portion of the delegated authority as appropriate.

## **Implementation of Strategic Plan Goals**

The recommended actions support Goal 2, Fiscal Sustainability of the County's Strategic Plan.

## **FISCAL IMPACT/FINANCING**

Since the inception of the Agreement in 2008, the Department has documented over \$25 million dollars in cost savings. Cardinal Health was initially reimbursed at a rate of ten percent of the realized savings of the PAP enrolments. However, effective January 1, 2012, this rate was reduced to eight percent by mutual agreement of the parties. Cardinal Health has agreed to accept this reduced rate for the extended Agreement term.

Based on DHS' projected savings of over \$9,000,000 for Fiscal Year (FY) 2012-13, the County's estimated cost for the remainder of FY 2012-13 is \$360,000, and \$720,000 per year thereafter, all offset by pharmaceutical cost savings. Funding is included in the DHS FY 2012-13 Final Budget, and will be requested in future fiscal years.

## **FACTS AND PROVISIONS/LEGAL REQUIREMENTS**

On December 18, 2007, the Board approved the initial Agreement to reduce the costs of pharmaceuticals dispensed to indigent patients. The Agreement was subsequently amended to extend the term on an annual basis through December 31, 2012, and add participating DHS pharmacies under delegated authority.

The Amendment adds the latest Board of Supervisors' required provisions not previously included in the base agreement or through previous amendments.

The County may terminate the Agreement for convenience upon 10 days prior written notice to Cardinal Health.

County Counsel has reviewed and approved Exhibit I as to use and form.

## **IMPACT ON CURRENT SERVICES (OR PROJECTS)**

Approval of the recommendation will allow the continued provision of Indigent Drug Recovery Services and resulting cost-savings to the County.

The Honorable Board of Supervisors

12/4/2012

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mitchell Katz". The signature is written in a cursive, flowing style.

Mitchell H. Katz, M.D.

Director

MHK:ck

Enclosures

c: Chief Executive Office  
County Counsel  
Executive Office, Board of Supervisors

INDIGENT DRUG RECOVERY SERVICES

AMENDMENT NO. 7

THIS AMENDMENT is made and entered into this \_\_\_\_\_ day  
of \_\_\_\_\_, 2012,

by and between

COUNTY OF LOS ANGELES  
(hereafter "County"),

and

CARDINAL HEALTH 110, INC.  
(hereafter "Contractor").

WHEREAS, reference is made to that certain document entitled  
"INDIGENT DRUG RECOVERY SERVICES ", dated January 1, 2008, and further  
identified as County Agreement No. H-703104, and any amendments thereto (all  
hereafter "Agreement"); and

WHEREAS, pursuant to California Health and Safety Code, Section 1441 and  
1445, County has established and operates, through its Department of Health Services  
(hereinafter "Department" or "DHS"), various County hospitals, multi-service ambulatory  
care centers, comprehensive health centers and health centers, including Harbor -  
UCLA Medical Center, LAC + USC Medical Center, Olive View - UCLA Medical Center,  
and Rancho Los Amigos National Rehabilitation Center; and

WHEREAS, the parties are desirous of amending the Agreement to extend the  
term of the Agreement to allow Indigent Drug Recovery Services to continue at  
participating County facilities, and

WHEREAS, the Agreement provides that changes may be made in the form of a written amendment which is formally approved and executed by the parties.

NOW, THEREFORE, the parties agree as follows:

1. This Amendment shall become effective January 1, 2013.
2. Paragraph 4.0, TERM OF CONTRACT, is revised to read as follows:
  - “4.1. The term of this Contract shall be effective January 1, 2008 through December 31, 2013, unless sooner terminated or extended, in whole or in part, as provided in this Contract.
  - 4.2. The County shall have the sole option to extend this Contract term for up to four (4) additional one-year periods, for a maximum total Contract term of ten (10) years. Each option and extension shall be exercised at the sole discretion of the Director of Health Services (hereafter referred to as “Director”), or his designee, as provided in subparagraph 8.1 of this Contract.
  - 4.3. The Contractor shall notify the Director when this Contract is within (6) months from the expiration of the term as provided for hereinabove. Upon occurrence of this event, the Contractor shall send written notification to Director at the address herein provided in Exhibit E-County’s Administration.
  - 4.4 The County maintains databases that track/monitor Contractor performance history. Information entered into such databases may be used for a variety of purposes, including determining whether the County

will exercise a contract term extension option. This Agreement may be extended only by a formal amendment.”

3. Subparagraph 8.25.3, FAILURE TO MAINTAIN COVERAGE, shall be replaced in its entirety to read as follows:

“8.25.3 Failure to Maintain Insurance

Contractor's failure to maintain or to provide acceptable evidence that it maintains the Required Insurance shall constitute a material breach of the Contract, upon which County immediately may withhold payments due to Contractor, and/or suspend or terminate this Contract. County, at its sole discretion, may obtain damages from Contractor resulting from said breach.”

4. Paragraph 8.52, CONTRACTOR'S WARRANTY OF COMPLIANCE WITH COUNTY'S DEFAULTED PROPERTY TAX REDUCTION PROGRAM, shall be added to read as follows:

“8.52 CONTRACTOR'S WARRANTY OF COMPLIANCE WITH  
COUNTY'S DEFAULTED PROPERTY TAX REDUCTION PROGRAM

8.52.1 Contractor acknowledges that County has established a goal of ensuring that all individuals and businesses that benefit financially from County through contract are current in paying their property tax obligations (secured and unsecured roll) in order to mitigate the economic burden otherwise imposed upon County and its taxpayers.

8.52.2 Unless Contractor qualifies for an exemption or exclusion,

Contractor warrants and certifies that to the best of its knowledge it is now in compliance, and during the term of this contract will maintain compliance, with Los Angeles Code Chapter 2.206.”

5. Paragraph 8.53, TERMINATION FOR BREACH OF WARRANTY TO MAINTAIN COMPLIANCE WITH COUNTY’S DEFAULTED PROPERTY TAX REDUCTION PROGRAM, shall be added to read as follows:

“8.53 TERMINATION FOR BREACH OF WARRANTY TO MAINTAIN COMPLIANCE WITH COUNTY’S DEFAULTED PROPERTY TAX REDUCTION PROGRAM

Failure of Contractor to maintain compliance with the requirements set forth in sub-paragraph 8.17 - Contractor’s Warranty of Compliance with County’s Defaulted Property Tax Reduction Program shall constitute default under this Agreement. Without limiting the rights and remedies available to County under any other provision of this Agreement, failure of Contractor to cure such default within 10 days of notice shall be grounds upon which County may terminate this Agreement and/or pursue debarment of Contractor, pursuant to County Code Chapter 2.206.”

6. Paragraph 9.1, CONTRACTOR’S OBLIGATIONS AS A “BUSINESS ASSOCIATE” UNDER HEALTH INSURANCE PORTABILITY & ACCOUNTABILITY ACT OF 1996 (HIPAA), shall be replaced in its entirety, and read as follows:

“9.1 HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY



ACT OF 1996 (HIPAA) AND THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT (HITECH): The County is subject to the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH). Under this Agreement, the Contractor provides services to the County and the Contractor receives, has access to, and/or creates Protected Health Information as defined in Exhibit N in order to provide those services. The County and the Contractor therefore agree to the terms of Exhibit J, Contractor's Obligations as a "Business Associate" Under Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) (Business Associate Agreement)."

7. Exhibit J, BUSINESS ASSOCIATE AGREEMENT, shall be replaced in its entirety, attached hereto and incorporated herein by reference.

Except for changes set forth hereinabove, the wording of the Agreement shall not be changed in any respect by this Amendment,

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IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be executed by its Director of Health Services and Contractor has caused this Amendment to be executed in its behalf by its duly authorized officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES

By \_\_\_\_\_  
Mitchell H. Katz, M.D.  
Director of Health Services

\_\_\_\_\_  
CARDINAL HEALTH 110, INC.  
Contractor

By \_\_\_\_\_  
Signature

\_\_\_\_\_  
Printed Name

APPROVED AS TO FORM:

+

John Krattli  
County Counsel

## **BUSINESS ASSOCIATE AGREEMENT**

### **CONTRACTOR'S OBLIGATIONS AS A "BUSINESS ASSOCIATE" UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA) AND THE HEALTH CARE INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT (HITECH)**

Under this Agreement, Contractor ("Business Associate") provides services ("Services") to County ("Covered Entity") and Business Associate receives, has access to or creates Protected Health Information in order to provide those Services.

Covered Entity is subject to the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), and regulations promulgated thereunder, including the Standards for Privacy of Individually Identifiable Health Information ("Privacy Regulations") and the Health Insurance Reform: Security Standards ("the Security Regulations") at 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164 (together, the "Privacy and Security Regulations"). The Privacy and Security Regulations require Covered Entity to enter into a contract with Business Associate ("Business Associate Agreement") in order to mandate certain protections for the privacy and security of Protected Health Information, and those Regulations prohibit the disclosure to or use of Protected Health Information by Business Associate if such a contract is not in place.

Further, pursuant to the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 ("HITECH Act"), effective February 17, 2010, certain provisions of the HIPAA Privacy and Security Regulations apply to Business Associates in the same manner as they apply to Covered Entity and such provisions must be incorporated into the Business Associate Agreement.

This Business Associate Agreement and the following provisions are intended to protect the privacy and provide for the security of Protected Health Information disclosed to or used by Business Associate in compliance with HIPAA's Privacy and Security Regulations and the HITECH Act, as they now exist or may hereafter be amended.

Therefore, the parties agree as follows:

#### **DEFINITIONS**

1.1 "Breach" has the same meaning as the term "breach" in 45 C.F.R. § 164.402.

- 1.2 “Disclose” and “Disclosure” mean, with respect to Protected Health Information, the release, transfer, provision of access to, or divulging in any other manner of Protected Health Information outside Business Associate’s internal operations or to other than its employees.
- 1.3 “Electronic Health Record” has the same meaning as the term “electronic health record” in the HITECH Act, 42 U.S.C. section 17921. Electronic Health Record means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.
- 1.4 “Electronic Media” has the same meaning as the term “electronic media” in 45 C.F.R. § 160.103. Electronic Media means (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission. The term “Electronic Media” draws no distinction between internal and external data, at rest (that is, in storage) as well as during transmission.
- 1.5 “Electronic Protected Health Information” has the same meaning as the term “electronic protected health information” in 45 C.F.R. § 160.103. Electronic Protected Health Information means Protected Health Information that is (i) transmitted by electronic media; (ii) maintained in electronic media.
- 1.6 “Individual” means the person who is the subject of Protected Health Information and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).
- 1.7 “Minimum Necessary” refers to the minimum necessary standard in 45 C.F.R. § 162.502 (b) as in effect or as amended.
- 1.8 “Privacy Rule” means the Standards for Privacy of Individually Identifiable Health Information at 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164, also referred to as the Privacy Regulations.

- 1.9 "Protected Health Information" has the same meaning as the term "protected health information" in 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity. Protected Health Information includes information that (i) relates to the past, present or future physical or mental health or condition of an Individual; the provision of health care to an Individual, or the past, present or future payment for the provision of health care to an Individual; (ii) identifies the Individual (or for which there is a reasonable basis for believing that the information can be used to identify the Individual); and (iii) is received by Business Associate from or on behalf of Covered Entity, or is created by Business Associate, or is made accessible to Business Associate by Covered Entity. "Protected Health Information" includes Electronic Health Information.
- 1.10 "Required By Law" means a mandate contained in law that compels an entity to make a Use or Disclosure of Protected Health Information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or any administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing benefits.
- 1.11 "Security Incident" means the attempted or successful unauthorized access, Use, Disclosure, modification, or destruction of information in, or interference with system operations of, an Information System which contains Electronic Protected Health Information. However, Security Incident does not include attempts to access an Information System when those attempts are not reasonably considered by Business Associate to constitute an actual threat to the Information System.
- 1.12 "Security Rule" means the Security Standards for the Protection of Electronic Health Information also referred to as the Security Regulations at 45 Code of Federal Regulations (C.F.R.) Part 160 and 164.
- 1.13 "Services" has the same meaning as in the body of this Agreement.
- 1.14 "Unsecured Protected Health Information" has the same meaning as the term "unsecured protected health information" in 45 C.F.R. § 164.402.

- 1.15 “Use” or “Uses” mean, with respect to Protected Health Information, the sharing, employment, application, utilization, examination or analysis of such Information within Business Associate’s internal operations.
- 1.16 Terms used, but not otherwise defined in this Business Associate Agreement shall have the same meaning as those terms in the HIPAA Regulations and HITECH Act.

## **OBLIGATIONS OF BUSINESS ASSOCIATE**

2.1 Permitted Uses and Disclosures of Protected Health Information. Business Associate:

(a) shall Use and Disclose Protected Health Information only as necessary to perform the Services, and as provided in Sections 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 4.3 and 5.2 of this Agreement;

(b) shall Disclose Protected Health Information to Covered Entity upon request;

(c) may, as necessary for the proper management and administration of its business or to carry out its legal responsibilities:

(i) Use Protected Health Information; and

(ii) Disclose Protected Health Information if the Disclosure is Required by Law.

Business Associate shall not Use or Disclose Protected Health Information for any other purpose or in any manner that would constitute a violation of the Privacy Regulations or the HITECH Act if so Used or Disclosed by Covered Entity.

2.2 Prohibited Uses and Disclosures of Protected Health Information. Business Associate:

(a) shall not Use or Disclose Protected Health Information for fundraising or marketing purposes.

(b) shall not disclose Protected Health Information to a health plan for payment or health care operations purposes if the Individual has requested this special restriction and has paid out of pocket in full for the health care item or service to which the Protected Health Information solely relates.

- (c) shall not directly or indirectly receive payment in exchange for Protected Health Information, except with the prior written consent of Covered Entity and as permitted by the HITECH Act. This prohibition shall not effect payment by Covered Entity to Business Associate. Covered Entity shall not provide such written consent except upon express approval of the departmental privacy officer and only to the extent permitted by law, including HIPAA and the HITECH Act.

2.3 Adequate Safeguards for Protected Health Information. Business Associate:

- (a) shall implement and maintain appropriate safeguards to prevent the Use or Disclosure of Protected Health Information in any manner other than as permitted by this Business Associate Agreement. Business Associate agrees to limit the Use and Disclosure of Protected Health Information to the Minimum Necessary in accordance with the Privacy Regulation's minimum necessary standard as in effect or as amended.
- (b) as to Electronic Protected Health Information, shall implement and maintain administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic Protected Health Information; effective February 17, 2010, said safeguards shall be in accordance with 45 C.F.R. Sections 164.308, 164.310, and 164.312, and shall comply with the Security Rule's policies and procedure and documentation requirements.

2.4 Reporting Non-Permitted Use or Disclosure and Security Incidents and Breaches of Unsecured Protected Health Information. Business Associate

- (a) shall report to Covered Entity each Use or Disclosure of Protected Health Information that is made by Business Associate, its employees, representatives, Agents, subcontractors, or other parties under Business Associate's control with access to Protected Health Information but which is not specifically permitted by this Business Associate Agreement or otherwise required by law.
- (b) shall report to Covered Entity each Security Incident of which Business Associate becomes aware.
- (c) shall notify Covered Entity of each Breach by Business Associate, its employees, representatives, agents or subcontractors of Unsecured Protected Health Information that is known to Business Associate or, by exercising reasonable diligence, would have been known to Business Associate. Business Associate shall be deemed to have knowledge of a Breach of Unsecured Protected Health Information if

the Breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the Breach, who is an employee, officer, or other agent of the Business Associate as determined in accordance with the federal common law of agency.

- 2.4.1 Immediate Telephonic Report. Except as provided in Section 2.4.3, notification shall be made immediately upon discovery of the non-permitted Use or Disclosure of Protected Health Information, Security Incident or Breach of Unsecured Protected Health Information by telephone call to [To Be Determined], telephone number 1(800) 711-5366.
- 2.4.2 Written Report. Except as provided in Section 2.4.3, the initial telephonic notification shall be followed by written notification made without unreasonable delay and in no event later than three (3) business days from the date of discovery of the non-permitted Use or Disclosure of Protected Health Information, Security Incident, or Breach by the Business Associate to the Chief Privacy Officer at:

Chief Privacy Officer  
Kenneth Hahn Hall of Administration  
500 West Temple Street  
Suite 525  
Los Angeles, California 90012  
HIPAA@auditor.lacounty.gov  
(213) 974-2166

- (a) The notification required by section 2.4 shall include, to the extent possible, the identification of each Individual whose Unsecured Protected Health Information has been, or is reasonably believed by the Business Associate to have been, accessed, acquired, Used, or Disclosed; and
- (b) The notification required by section 2.4 shall include, to the extent possible, all information required to provide notification to the Individual under 45 C.F.R. 164.404(c), including:
- (i) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;



- (ii) A description of the types of Unsecured Protected Health Information that were involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
- (iii) Any other details necessary to conduct an assessment of whether there is a risk of harm to the Individual;
- (iv) Any steps Business Associate believes that the Individual could take to protect him or herself from potential harm resulting from the breach;
- (v) A brief description of what Business Associate is doing to investigate the Breach, to mitigate harm to the Individual, and to protect against any further Breaches; and
- (vi) The name and contact information for the person most knowledgeable regarding the facts and circumstances of the Breach.

If Business Associate is not able to provide the information specified in section 2.3.2 (a) or (b) at the time of the notification required by section 2.4.2, Business Associate shall provide such information promptly thereafter as such information becomes available.

2.4.3 Request for Delay by Law Enforcement. Business Associate may delay the notification required by section 2.4 if a law enforcement official states to Business Associate that notification would impede a criminal investigation or cause damage to national security. If the law enforcement official's statement is in writing and specifies the time for which a delay is required, Business Associate shall delay notification, notice, or posting for the time period specified by the official; if the statement is made orally, Business Associate shall document the statement, including the identity of the official making the statement, and delay notification, notice, or posting temporarily and no longer than 30 days from the date of the oral statement, unless a written statement as described in paragraph (a) of this section is submitted during that time.

2.5 Mitigation of Harmful Effect. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate

of a Use or Disclosure of Protected Health Information by Business Associate in violation of the requirements of this Business Associate Agreement.

2.6 Breach Notification. Business Associate shall, to the extent Covered Entity determines that there has been a Breach of Unsecured Protected Health Information, provide Breach notification for each and every Breach of Unsecured Protected Health Information by Business Associate, its employees, representatives, agents or subcontractors, in a manner that permits Covered Entity to comply with its obligations under Subpart D, Notification in the Case of Breach of Unsecured PHI, of the Privacy and Security Regulations, including:

- (a) Notifying each Individual whose Unsecured Protected Health Information has been, or is reasonably believed to have been, accessed, acquired, Used, or Disclosed as a result of such Breach;
- (b) The notification required by paragraph (a) of this Section 2.6 shall include, to the extent possible:
  - (i) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
  - (ii) A description of the types of Unsecured Protected Health Information that were involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
  - (iii) Any steps the Individual should take to protect him or herself from potential harm resulting from the Breach;
  - (iv) A brief description of what Business Associate is doing to investigate the Breach, to mitigate harm to individuals, and to protect against any further Breaches; and
  - (v) Contact procedures for Individual(s) to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.
  - (vi) The notification required by paragraph (a) of this section shall be written in plain language.

Covered Entity, in its sole discretion, may elect to provide the notification required by this Section 2.6, and Business Associate shall reimburse Covered Entity any and all costs incurred by Covered Entity, including costs of notification, internet posting, or media publication, as a result of Business Associate's Breach of Unsecured Protected Health Information.

- 2.7 Availability of Internal Practices, Books and Records to Government Agencies. Business Associate agrees to make its internal practices, books and records relating to the Use and Disclosure of Protected Health Information available to the Secretary of the federal Department of Health and Human Services for purposes of determining Covered Entity's compliance with the Privacy and Security Regulations. Business Associate shall immediately notify Covered Entity of any requests made by the Secretary and provide Covered Entity with copies of any documents produced in response to such request.
- 2.8 Access to Protected Health Information. Business Associate shall, to the extent Covered Entity determines that any Protected Health Information constitutes a "designated record set" as defined by 45 C.F.R. § 164.501, make the Protected Health Information specified by Covered Entity available to the Individual(s) identified by Covered Entity as being entitled to access and copy that Protected Health Information. Business Associate shall provide such access for inspection of that Protected Health Information within two (2) business days after receipt of request from Covered Entity. Business Associate shall provide copies of that Protected Health Information within five (5) business days after receipt of request from Covered Entity. If Business Associate maintains an Electronic Health Record, Business Associate shall provide such information in electronic format to enable Covered Entity to fulfill its obligations under the HITECH Act.
- 2.9 Amendment of Protected Health Information. Business Associate shall, to the extent Covered Entity determines that any Protected Health Information constitutes a "designated record set" as defined by 45 C.F.R. § 164.501, make any amendments to Protected Health Information that are requested by Covered Entity. Business Associate shall make such amendment within ten (10) business days after receipt of request from Covered Entity in order for Covered Entity to meet the requirements under 45 C.F.R. § 164.526.
- 2.10 Accounting of Disclosures. Upon Covered Entity's request, Business Associate shall provide to Covered Entity an accounting of each Disclosure of Protected Health Information made by Business Associate or its employees, agents, representatives or subcontractors, in order to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance

with 45 C.F.R. § 164.528 and/or the HITECH Act which requires an Accounting of Disclosures of Protected Health Information maintained in an Electronic Health Record for treatment, payment, and health care operations.

*[Optional, to be used when all Uses and Disclosures permitted in order to perform the Services will be for the Covered Entity's payment or health care operations activities: However, Business Associate is not required to provide an Accounting of Disclosures that are necessary to perform the Services because such Disclosures are for either payment or health care operations purposes, or both.]*

Any accounting provided by Business Associate under this Section 2.10 shall include: (a) the date of the Disclosure; (b) the name, and address if known, of the entity or person who received the Protected Health Information; (c) a brief description of the Protected Health Information disclosed; and (d) a brief statement of the purpose of the Disclosure. For each Disclosure that could require an accounting under this Section 2.10, Business Associate shall document the information specified in (a) through (d), above, and shall securely maintain the information for six (6) years from the date of the Disclosure. Business Associate shall provide to Covered Entity, within ten (10) business days after receipt of request from Covered Entity, information collected in accordance with this Section 2.10 to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528. If Business Associate maintains an Electronic Health Record, Business Associate shall provide such information in electronic format to enable Covered Entity to fulfill its obligations under the HITECH Act.

- 2.11 Indemnification. Business Associate shall indemnify, defend, and hold harmless Covered Entity, including its elected and appointed officers, employees, and agents, from and against any and all liability, including but not limited to demands, claims, actions, fees, costs, penalties and fines (including regulatory penalties and/or fines), and expenses (including attorney and expert witness fees), arising from or connected with Business Associate's acts and/or omissions arising from and/or relating to this Business Associate Agreement; Business Associate's obligations under this provision extend to compliance and/or enforcement actions and/or activities, whether formal or informal, of Secretary of the federal Department of Health and Human Services and/or Office for Civil Rights.

### 3.0 OBLIGATION OF COVERED ENTITY

- 3.1 Obligation of Covered Entity. Covered Entity shall notify Business Associate of any current or future restrictions or limitations on the use of Protected Health Information that would affect Business Associate's performance of the Services, and Business Associate shall thereafter restrict or limit its own uses and disclosures accordingly.

### 4.0 TERM AND TERMINATION

- 4.1 Term. The term of this Business Associate Agreement shall be the same as the term of this Agreement. Business Associate's obligations under Sections 2.1 (as modified by Section 4.2), 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 4.3 and 5.2 shall survive the termination or expiration of this Agreement.
- 4.2 Termination for Cause. In addition to and notwithstanding the termination provisions set forth in this Agreement, upon either party's knowledge of a material breach by the other party, the party with knowledge of the other party's breach shall:
- (a) Provide an opportunity for the breaching party to cure the breach or end the violation and terminate this Agreement if the breaching party does not cure the breach or end the violation within the time specified by the non-breaching party;
  - (b) Immediately terminate this Agreement if a party has breached a material term of this Agreement and cure is not possible; or
  - (c) If neither termination nor cure is feasible, report the violation to the Secretary of the federal Department of Health and Human Services.
- 4.3 Disposition of Protected Health Information Upon Termination or Expiration.
- (a) Except as provided in paragraph (b) of this section, upon termination for any reason or expiration of this Agreement, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.
  - (b) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make infeasible. If return or destruction is infeasible, Business Associate

shall extend the protections of this Business Associate Agreement to such Protected Health Information and limit further Uses and Disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

## 5.0 MISCELLANEOUS

- 5.1 No Third Party Beneficiaries. Nothing in this Business Associate Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.
- 5.2 Use of Subcontractors and Agents. Business Associate shall require each of its agents and subcontractors that receive Protected Health Information from Business Associate, or create Protected Health Information for Business Associate, on behalf of Covered Entity, to execute a written agreement obligating the agent or subcontractor to comply with all the terms of this Business Associate Agreement.
- 5.3 Relationship to Services Agreement Provisions. In the event that a provision of this Business Associate Agreement is contrary to another provision of this Agreement, the provision of this Business Associate Agreement shall control. Otherwise, this Business Associate Agreement shall be construed under, and in accordance with, the terms of this Agreement.
- 5.4 Regulatory References. A reference in this Business Associate Agreement to a section in the Privacy and/or Security Regulations means the section as in effect or as amended.
- 5.5 Interpretation. Any ambiguity in this Business Associate Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy and Security Regulations.
- 5.6 Amendment. The parties agree to take such action as is necessary to amend this Business Associate Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy and Security Regulations and other privacy laws governing Protected Health Information